

**REMARKS**

Claims 29-36 are pending in this application. Claim 29 has been amended. New claims 37-44 are submitted herewith. No new matter has been added by virtue of this amendment. Basis for this amendment can be found in the specification starting at page 5, line 14 through page 6, line 19.

**Nonstatutory Obviousness-Type Double Patenting**

In response to the Examiner's rejection based on Double Patenting, Applicants have filed herewith a Terminal Disclaimer with respect to US Patent No. 6,660,754 to Kyle et al. In light of this Terminal Disclaimer, Applicants believe that the rejection based on nonstatutory obviousness-type double patenting has been overcome. Therefore, Applicants respectfully request that this rejection be withdrawn.

**35 USC §112**

The Examiner has rejected claims 29-36 under 35 USC §112 as not being properly enabled for the use of the term "eliminating". Claim 29 has been amended to modify the phrase "eliminating tobacco usage" to the phrase "reducing tobacco usage" which according to the Examiner is sufficiently enabled by the specification. The Examiner makes reference to Claim 6 at page 6 of the specification, however, Applicants believe this is in error as there is no Claim 6 pending in the present application. In light of this amendment, Applicants respectfully ask for withdrawal of this rejection.

**35 USC §103**

The Examiner has rejected Claims 29-36 under 35 USC §103 as being obvious in light of US Patent 5,055,478 to Cooper et al.

The MPEP states that in order to establish a *prima facie* case of obviousness, three basic criteria must be met. See MPEP §2142. First, there must be some suggestion or motivation, either within the references themselves or the knowledge generally available to one of skill in the art, to modify or combine the reference(s) to reach the claimed invention. See *Id.* Second, there must be a reasonable expectation of success. *Id.* Lastly, the reference(s) must teach or suggest each and every element of the claim(s) at issue. See *Id.* In the instant case, the reference cited by the Examiner fails to teach or suggest each and every limitation of the claim. Therefore, the

Examiner has not met the burden of establishing a *prima facie* case of obviousness.

Cooper teaches a method for eliminating tobacco usage by gradually decreasing tobacco consumption over a period of time until no further tobacco is consumed. This is accomplished by breaking each day down into sequential consumption periods and replacing the nicotine obtained from tobacco usage with nicotine from an alternative nicotine source for an entire consumption period. Each subsequent day, the individual is deprived of nicotine from tobacco during the an additional consumption period in sequence. Once tobacco usage is eliminated by this method, the use of the nicotine alternative source is eliminated using the same sequential time period method, however, the individual maintains each reduction level for a period of one week, rather than just one day as with the tobacco reduction levels.

The Examiner asserts that while Cooper does not expressly teach the method of the present invention, it would have been obvious to combine the method of Cooper with the steps taught by the present invention. See page 11, paragraph 1 of the Office Action dated January 3, 2007. This involves hindsight reasoning which is impermissible when determining obviousness. As stated above, in order to show obviousness, each and every element of the claimed invention must be found within the cited reference(s) and not, with the benefit of hindsight reasoning, by combining the references with Applicant's own invention. In addition, the Examiner seems to indicate that one of skill need only optimize the teachings of Cooper to achieve the present invention; however, this oversimplifies the differences between the present invention and Cooper. Optimization of the Cooper regime, still does not render each and every element of the claimed invention.

The present invention relates to methods of reducing tobacco and, ultimately, nicotine alternative source usage, which is the same result sought in Cooper. However, the elimination of the alternative nicotine source usage is achieved by very different means in the present invention. As stated above, Cooper progressively eliminates nicotine derived from an alternative nicotine source by eliminating the administration of the alternative nicotine source from sequential consumption periods each progressive week until no further alternative nicotine source is consumed. See *Cooper* at column 7, lines 11-37 and column 9, lines 34-65. For example, during the first week of the elimination phase no alternative nicotine source is administered for the first consumption period of the day. During the second week no alternative

nicotine source is administered for the first two consumption periods of the day, and so forth. As a result of this method, however, the individual who is attempting to wean him or herself from the nicotine is forced to wait for longer and longer periods of time after waking before the alternative nicotine source can be administered. For instance 10 weeks into the nicotine elimination phase, the individual must wait 10 hours after waking before obtaining nicotine from any source – and then receives nicotine for the rest of the day. Importantly, this regimen may be very difficult to adhere to for an individual still nicotine dependent and facing nicotine cravings and may more easily fall into relapse.

In contrast, the method of the instant invention allows the individual to continue to consume the alternative nicotine source periodically throughout the entire day, but with reduced frequency. For example, once tobacco use ceases, the individual reduces intake of the alternative nicotine source from one unit per hour to one unit every one to two hours during the second predetermined period of time. In the third predetermined period of time, the individual consumes one unit of alternative nicotine source every two to four hours. In the fourth predetermined time period one unit of alternative nicotine source is consumed every four to eight hours. Subsequently the individual ceases consumption of the alternative nicotine source altogether. This is significantly different from the method described by Cooper and helps to eliminate compliance problems that may result from depriving an individual of nicotine for long periods at the start of the day. Cooper does not teach or suggest the reduction regimen as claimed herein as the focus in Cooper is the elimination of the alternative nicotine source from successive consumption periods. Thus, Cooper does not render obvious the present invention.

For the reasons stated above, Applicants assert that the present invention is not rendered obvious by U.S. Patent 5,055, 478 to Cooper et al and respectfully request withdrawal of the rejection under 103(a).


### **CONCLUSION**

In view of these amendments and remarks, as well as the Terminal Disclaimer submitted herewith, Applicants believe all bases for rejections raised by the Examiner in the Office Action dated January 3, 2007, have been

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fully addressed and remedied. Applicants respectfully request allowance of all claims pending in this application.

Respectfully submitted,



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